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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/604,227	07/02/2003	Jeffrey Grossman	31132.164	1226

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EXAMINER

POUS, NATALIE R

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 07/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	10/604,227		GROSSMAN, JEFFREY	
	Examiner		Art Unit	
	Natalie Pous		3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1 and 3-21 is/are allowed.
- 6) ☒ Claim(s) 22,24-26,29 and 30 is/are rejected.
- 7) ☒ Claim(s) 27 and 28 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/22/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Examiner acknowledges the submission of amended claims 1 and 3-21, and the submission of new claims 22-30.

Regarding the 35 USC 112 rejection

Examiner acknowledges the amendment to claim 1 to include an indication surface. As such, the previous 112 rejection is withdrawn

Regarding the 35 USC 102 rejections

Applicant's arguments, see pages 6-9, filed 12/19/05, with respect to Karram have been fully considered and are persuasive. The 35 USC 102(b) of claims 1, 3-9, 11, 12, 13 has been withdrawn.

Applicant's arguments, see pages 6-9, filed 12/19/05, with respect to Burgin have been fully considered and are persuasive. The 35 USC 102(b) of claims 1, 3-9, 13-16 and 19-21 has been withdrawn.

Applicant's arguments, see pages 6-9, filed 12/19/05, with respect to Burgin have been fully considered and are persuasive. The 35 USC 102(b) of claims 18-21 has been withdrawn.

Regarding the 35 USC 103 rejections

Applicant's arguments, see pages 9-13, filed 12/19/05, with respect to the combination of Karram and Pirtle have been fully considered and are persuasive. The 35 USC 103(a) of claim 10 has been withdrawn.

Applicant's arguments, see pages 9-13, filed 12/19/05, with respect to the combination of Kitaevich and Yanof have been fully considered and are persuasive. The 35 USC 103(a) of claims 13 and 17 has been withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 22, 24, 25, 26, 29 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Karram et al. (US 6428180).

Regarding Claim 22 Karram teaches a system capable of aligning an instrument (100) for use in treating a patient, comprising: an instrument (100) having a working end (100) and an opposite proximal end (104); an energy source (102) adapted to selectively engage a portion of the instrument (Column 2, proximate lines 30-35) and for producing an energy path in a direction away from the working end (see fig. 1, the path of light 108 diffuses away from the working end of the device); and a surface (114) for indicating the trajectory of the energy path, the trajectory of the energy path correlating to a trajectory of the instrument (it is noted that as the light source is parallel with the tool, the trajectory of the energy path produced by the light source is the trajectory of the instrument)

Regarding claim 24, Karram teaches the device of claim 22, wherein the working end includes a cutting portion (fig. 1)

Regarding Claim 25, Karram teaches the device of claim 22, further including a longitudinal axis extending at least partially between the working end and the proximal end. (it is noted that instrument 100 is planar and therefore has a longitudinal axis extending at least partially through it)

Regarding Claim 26, Karram teaches the system of claim 25 wherein the energy source (102) is adapted to produce an energy path substantially parallel to the longitudinal axis (fig. 1)

Regarding Claim 29, Karram teaches the system of claim 22, wherein the energy source (102) is a light source

Regarding Claim 30, Karram teaches the system of claim 29, wherein the energy source is adapted to selectively engage the proximal end of the instrument (see claim 1).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Karram in view of Pirtle (US 3628523). Karram discloses all aspects of claim 22 as disclosed above but does not disclose that the work piece be a needle. Karram does however disclose that the surgical illumination device is detachably mountable in a variety of ways on any suitable surgical instrument (Column 2, proximate lines 45-55). Pirtle discloses a percutaneous needle (Column 1, proximate lines 55-65). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Karram with a percutaneous needle as taught by Pirtle in order to fulfill the devices capability of use on any surgical instrument.

Allowable Subject Matter

Claims 27 and 28 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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Claims 1 and 3-23 are allowed. The following is an examiner's statement of reasons for allowance:

Independent claims 1, 13 and 18 are patentable over the prior art because the prior art fails to teach an alignment system for an insertion device wherein the energy path is directed away from the patient, reflected or viewed on a surface such that the proximity of the reflected path to the energy source indicates any alignment correction required. Prior art cited reference Karram (US 6428180) teaches an insertion device comprising an energy source for producing an energy path in a direction away from the instrument (see above), however regarding claims 1 and 13, Karram fails to disclose or suggest a configuration wherein the energy source is directed away from the patient, as the purpose of the device is to produce the energy path in the direction towards the patient. Regarding claims 13 and 18, Karram further fails to disclose or suggest a reflective element and a surface indicating the proximity of the reflected energy path to the energy source to indicate any alignment correction required for the instrument.

Prior cited reference Burgin (US 4657012) teaches an insertion device wherein an energy source produces an energy path away from the working end of the device, but like Karram, regarding claims 1 and 13, Burgin fails to disclose or suggest a configuration wherein the energy source is directed away from the patient, as the purpose of the device is to produce the energy path in the direction towards the patient. And regarding claims 13 and 18, although Burgin does teach a reflective element and a surface, the two in conjunction fail to indicate the proximity of the reflected energy path to the energy source to indicate any alignment correction required for the instrument.

Prior cited reference Paltieli (US 5647373) teaches an insertion device wherein an energy source produces an energy path away from the working end of the device, but does not teach wherein the energy source is directed away from the patient, as the purpose of the device is to produce the energy path in the direction towards the patient.

Subsequently, dependent claims 3-12, 14-17, and 19-21 are allowable.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie Pous whose telephone number is (571) 272-6140. The examiner can normally be reached on Monday-Friday 8:00am-5:30pm, off every 2nd Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NRP
6/29/06


JACKIE TAN-UYEN HO
PRIMARY EXAMINER
7/3/06